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June 19, 2002

Honorable Commissioner of  
Patents and Trademarks  
Washington, DC 20231

Re: U.S. Utility Patent Application  
Appl. No. 09/760,897; Filed: January 17, 2001  
For: Compositions and Methods for Non-Targeted Activation of  
Endogenous Genes  
Inventor(s): Harrington et al  
Our Ref: 0221-0003O(c)

RECEIVED  
JUN 25 2002  
OFFICE OF PETITIONS

Sir:

Transmitted herewith for appropriate action are the following documents:

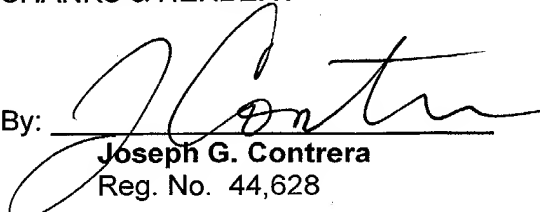
1. Transmittal Letter to the USPTO;
2. Reply To Decision Dismissing Petition For Filing Date;
3. Exhibit 1: 1 Copy of the Application as filed in the parent case;
4. Exhibit 2: Preliminary Amendment filed with the USPTO on February 25, 2000;
5. Exhibit 3: 1 Copy of the Cover Sheet for the Continuation Application filed with the USPTO on January 17, 2001;
6. Exhibit 4: 1 Copy of the Preliminary Amendment documents filed March 27, 2001; and
7. 1 return postcard

The Commissioner is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 50-0622.

Respectfully submitted,

SHANKS & HERBERT

By:

  
Joseph G. Contrera  
Reg. No. 44,628

JGC:km  
Encl.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



On re Application of: Harrington *et al.*

Appl. No. 09/760,897

Filed: January 17, 2001

For: **Compositions and Methods for Non-Targeted Activation of Endogenous Genes**

Art Unit: 1655

Examiner: B. Forman

Atty. Docket: 0221-0003OC

#15

**REPLY TO DECISION DISMISSING PETITION FOR A FILING DATE IN  
RESPONSE TO THE NOTICE OF OMITTED ITEM(S) IN A  
NONPROVISIONAL APPLICATION**

Assistant Commissioner for Patents  
Box DAC  
Washington, D.C. 20231

Sir:

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Applicants respectfully submit herewith their reply to the Decision Dismissing Applicants Petition (hereinafter, "the Dismissal") requesting that the U.S. Patent & Trademark Office accord the filing date of January 17, 2001 to all 166 pages of the specification of the above-identified continuation application including allegedly omitted pages 53 and 54. Applicants also wish to thank the Petitions Examiner for his helpful comments during our telephone conversation of June 18, 2002.

In the Dismissal, the Petitions Examiner was not persuaded by Applicant's evidence that the continuation application was filed with the missing pages, which consisted of, *inter alia*, copies of the PTO stamped postcard identifying that applicants had provided a copy of the specification of the parent application as filed. A copy of the parent application (09/515,124), was retrieved from the PTO file and does in fact, contain

missing pages 53 and 54. A copy of the '124 application was included in the original petition. The Petitions Examiner stated that because the postcard did not indicate that the specification contained 166 pages, it did not qualify a *prima facie* evidence or receipt of the entire document at the USPTO under MPEP 503. (Dismissal, p. 2)

In addition, the Petitions Examiner advised that if the Applicants had included a statement in the transmittal letter or elsewhere in the application that specifically incorporates by reference the entire disclosure of the prior application, for which an oath or declaration is supplied, this problem could have been avoided. (Dismissal, p.3) Applicants respectfully point out that this was, in fact, done in the instant application.

The Petitions Examiner's attention is directed to the copy of the parent application 09/515,124 (filed 2/27/2000), which was included in Applicant's original petition as Exhibit 3. The '124 application was not missing pages 53 and 54. The first paragraph of the '124 application states:

This Application is a continuation-in-part of U.S. Application No. \_\_\_\_\_ of John J. Harrington, Bruce Sherf, and Stephen Rundlett, entitled, "Compositions and Methods for Non-targeted Activation of Endogenous Genes" filed March 8, 1999, which is a continuation-in-part of U.S. Application No. 09/253,022, filed February 19, 1999, which is a continuation-in-part of U.S. Application No. 09/159,643, filed September 24, 1998, which is a continuation-in-part of U.S. Application No. 08/941,223, filed September 26, 1997, *the disclosures of all of which are incorporated herein by reference in their entireties.* (emphasis added)

A copy of this specification, as retrieved from the PTO's files by our contractor, Digipat, is provided as Exhibit 1 of this Reply for the convenience of the Petitions Examiner. Note that the paragraph does include the language advised by the Examiner in the

Dismissal, regarding incorporating the disclosures of the parent applications by reference in the specification. (Exhibit 1, p. 1).

At the time the parent '124 application was filed, a preliminary amendment was also filed which amended the specification as follows:

In the specification at page 1, line 4, after the words "This application" and before "is", please insert --is a divisional application of U.S. Application No. 09/276,820, filed March 26, 1999, entitled "COMPOSITIONS AND METHODS FOR NON-TARGETED ACTIVATION OF ENDOGENOUS GENES" which--; and on line 5, in the blank, please insert --09/263,814--. (Exhibit 2, p. 1)

Thus the '124 application claimed priority to the two parent applications and incorporated them by reference in the their entireties as well. As stated previously, the '124 application contains the missing pages 53 and 54.

On January 17, 2001, Applicants filed a continuation application (09/760,897) to the '124 application. The '897 application is the application which appears to have pages 53 and 54 missing from its specification, and is the subject of Applicant's petition. The cover sheet of the continuation application identifies the '897 application as a continuation of the '124 application. (Exhibit 3, p.2). The cover sheet also contains a preliminary amendment to the specification of the continuation application, which states:

--This is a continuation of application Serial No. 09/515,124 filed February 27, 2000.— (Exhibit 3, p. 3)

Both preliminary amendments of the '124 and '897 applications were entered respectively. Therefore, at the time the '897 application was filed, the paragraph of the specification that cross-referenced related applications read as follows:

This is a continuation of application Serial No. 09/515,124 filed February 27, 2000. This Application is a divisional application of U.S. Application No. 09/276,820, filed March 26, 1999, entitled "COMPOSITIONS AND METHODS FOR NON-TARGETED ACTIVATION OF ENDOGENOUS GENES" which is a continuation-in-part of U.S. Application No. 09/263,814 of John J. Harrington, Bruce Sherf, and Stephen Rundlett, entitled, "Compositions and Methods for Non-targeted Activation of Endogenous Genes" filed March 8, 1999, which is a continuation-in-part of U.S. Application No. 09/253,022, filed February 19, 1999, which is a continuation-in-part of U.S. Application No. 09/159,643, filed September 24, 1998, which is a continuation-in-part of U.S. Application No. 08/941,223, filed September 26, 1997, the disclosures of all of which are incorporated herein by reference in their entirety.

Finally, on March 27, 2001, Applicants again amended the specification of the '897 application in another preliminary amendment. (Exhibit 4). The sole purpose of this preliminary amendment was to clean up the "Cross-reference to Related Applications" section of the '897 application after multiple amendments through various related applications. No substantive information was added or changed. The amended section of the '897 application, as currently pending, now reads (in mark-up form):

This is a continuation of U.S. Serial No. 09/515,124, filed February 27, 2000, entitled "Compositions and Methods for Non-Targeted Activation of Endogenous Genes," naming John J. Harrington, Bruce Sherf, and Stephen Rundlett as inventors, which is a divisional application of U.S. Application No. 09/276,820, filed March 26, 1999, which is a continuation-in-part of U.S. Application No. 09/263,814, [This is a continuation of application Serial No. 09/515,124 filed February 27, 2000. This application is a continuation-in-part of U.S. Application No. \_\_\_\_\_ of John J. Harrington, Bruce Sherf, and Stephen Rundlett, entitled "Compositions and Methods for Non-targeted Activation of Endogenous Genes,"] filed March 8, 1999, which is a continuation-in-part of U.S. Application No. 09/253,022, filed February 19, 1999, which is a continuation-in-part of U.S. Application No. 09/159,643, filed September 24, 1998, which is a continuation-in-part of U.S. Application No. 08/941,223, filed September 26, 1997, *the disclosures of all of which are incorporated herein by reference in their entirety.* (Exhibit 4, p. 4). (emphasis added)

Clearly, the '897 application contains the language necessary to incorporate all of the previous related application in its specification by reference.

The relevant portions of MPEP § 201.06(c) states as follows:

...[A]pplicants may incorporate by reference the prior application by including, in the continuation or divisional application-as-filed, a statement that such specifically enumerated prior application or applications are "hereby incorporated herein by reference." The statement may appear in the specification or in the application transmittal letter. The incorporation by reference statement can only be relied upon to permit the entering of a portion of the prior application into the continuation or divisional application when the portion of the prior application has been inadvertently omitted from the submitted application papers in the continuation or divisional application. The inclusion of this incorporation by reference of the prior application(s) will permit an applicant to amend the continuation or divisional application to include any subject matter in such prior application(s), without the need for a petition provided the continuation or divisional application is entitled to a filing date notwithstanding the incorporation by reference...for the incorporation by reference to be effective as a proper safeguard against the omission of a portion of a prior application, the incorporation by reference statement must be included in the specification-as-filed, or transmittal letter-as-filed, or in an amendment specifically referred to in an oath or declaration executing the application...

The requirements of this section are that: (1) Applicants properly incorporated the missing portion of the prior application (pages 53 and 54) in the specification as filed or transmittal letter as filed; and (2) that the continuation application is entitled to a filing date notwithstanding the incorporation by reference. Applicants respectfully submit that they have complied with these requirements of MPEP § 201.06(c).

The evidence put forth by Applicants herein shows that the specification of the '897 application properly claimed priority to related applications and incorporated the disclosures of all by reference in their entireties, including the parent '124 application

which contains the missing pages 53 and 54, thereby satisfying the first requirement of MPEP § 201.06(c). (Exhibit 1, p. 1).

Furthermore, the '897 application is entitled to its January 17, 2001 filing date notwithstanding the missing pages 53 and 54. Inspection of the missing pages shows that these pages are at the beginning of the detailed description section of the specification, and provide only a general description by the Applicants, of cells made using the invention of various species of eukaryotes and preferred cell lines, and general methods of derivation and use of these cells. The detailed description continues for another 100 pages, and the actual examples of embodiments do not begin until page 119 of the specification. These pages are not critical for the claimed invention, and therefore, Applicants have satisfied the second requirement of MPEP § 201.06(c).

In light of the above facts and argument, Applicants respectfully request the Petitions Examiner to reverse his Dismissal and grant the '897 application its original filing date of January 17, 2001, and allow pages 53 and 54 to be added to its specification by amendment.

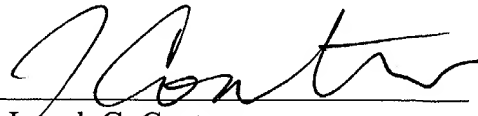
Prompt and favorable consideration of this Petition and the cited documents and making the same of record in the prosecution of the above-noted application is respectfully requested.

The Commissioner is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 50-0622.

Appl. No. 09/760,897  
Atty. Dkt. No. 0221-0003OC

Respectfully submitted,

SHANKS & HERBERT

By:   
Joseph G. Contrera  
Reg. No. 44,628

Date: 6/19/02

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